nd to a collection of information unless it contains a valid OMB control number.

	Application Number	10595385
	Filing Date	2006-04-13
INFORMATION DISCLOSURE	First Named Inventor	Marcus A. Horwitz
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit	
(Not for submission under 57 Of K 1.33)	Examiner Name	
	Attorney Docket Numb	er 51326-00019

			Remove			
Examiner Cite Patent Number Kir Co		Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevan Figures Appear	
	1	5504005		1996-04-02	Bloom et al.	
	2	5583038		1996-12-10	Stover	
	3	5591632		1997-01-07	O'Donnell et al.	
	4	5679515		1997-10-21	Stover et al.	
	5	5700683		1997-12-23	Stover et al.	
	6	5736367		1998-04-07	Haun et al.	
	7	5776465		1998-07-07	O'Donnell et al.	
	8	5807723		1998-09-15	Aldovini et al.	

INFORMATION DISCLOSURE			First N	First Named Inventor Marcus A. Horwitz									
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)			Art Unit										
(Not for submission under 37 CFR 1.99)			Examiner Name								\neg		
				Attorn	Attorney Docket Number 51326-00019						\neg		
	9	5830475		1998-11	1-03	Aldovini e	t al.						
	10	5854055		1998-12	2-29	9 Bloom et al.							
	11	5866403		1999-02	2-02	Aldovini et al.							
	12	5869057		1999-02	9-02-09 Rock								
	13	6015696		2000-0	1-18	Yamada o	t al.						
	14	6471967	B1	2002-10	0-29	Horwitz et	al.						
If you wis	h to ac	d additional U.S. Pater	t citatio	n inform	ation pl	ease click	the	Add button.			Add		
			U.S.P.	ATENT	APPLI	CATION P	UBL	ICATIONS			Remove		
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publica Date	ition	Name of of cited D		ntee or App ment	Micant	Releva		Lines whe ges or Rele	
	1												
If you wis	h to ac	d additional U.S. Publi	shed Ap	plication	citation	n informati	on p	lease click t	the Add	button	$\overline{}$		
				FOREIG	SN PAT	ENT DOC	UM	ENTS			Remove		
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²		Kind Code ⁴	Publicatio Date	ın	Name of Pa Applicant o Document		or	vhere Rel	or Releva	T.

Application Number

Filing Date

10595385

2006-04-13

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 199) Examiner Name

Application Number	10595385
Filing Date	2006-04-13
First Named Inventor N	Marcus A. Horwitz
Art Unit	
Examiner Name	
Attorney Docket Number	51326-00019

	1	2004/031356	wo		2004-04-15	The Regents of the University of California			
	2	88/06626	wo		1988-09-07	Whitehead Institute for Biomedical Research			
If you wis	h to a	dd additional Foreign P	atent Document	citation	information pl	ease click the Add button	Add		
			NON-PATE	NT LITE	ERATURE DO	CUMENTS	Remove	1	
Examiner Initials*	Cite No		nal, serial, symp	osium,	catalog, etc), o	the article (when appropr date, pages(s), volume-is			Тŝ
	1 CIRLLO et al., "Bacrerial Vaccine Vectors and Bacillus Calmetin-Guern", Clinical Infectious Diseases, 20:1001-9 (1995)								
	2 RUERST et al., "Development and Analysis of Recombinant BCG Vector Systems", AIDS Research and Human Retroviruses, 8:1451-5 (1992)								
	3	HANSON et al., *Efficac	y and Safety of Li	ve Reco	mbinant BCG V	accines", Dev. Biol. Stand.,	84:229-36 (1995)	
	HARTH et al., "High-Level Heterologius Expression and Secretion in Rapidly Growing Nonpathogenic Mycobacteria of Four Major Mycobacterium Tuberologia Estacealistic Proteins Considered to be Leading Vaccine Candidates and Drug Targess," reference and termunity, 62:2214-6 (1997)								
	5 HARTH et al., "Novel braights info the Genetics, Biochemistry, and Immunocytochemistry of the 30 Kilodation Major Extracellular Protein of Mycobacterium Tuberculosia", infection and Immunity, 64:3038-47 (1668)								
	6	Tuberculosis 30-kDa Ma	ajor Secretory Pro	tem Indu	uce Greater Prot	/accines Expressing the My lective Immunity Against Tut In, PNAS, 97:13853-8 (2000)	erculosis T		
	LANGERMANN et al., "Protective Humoral Response Against Pneumococcal Infection in Mice Elicited by 7 Recombinant Badile Calmette-Guerin Vaccines Expressing Pneumococcal Surface Protein A.", J Exp Med., 180/2277-86 (1984).								

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number		10595385
iling Date		2006-04-13
irst Named Inventor	Marc	us A. Horwitz
Art Unit		
xaminer Name		
Attorney Docket Numb	er	51326-00019

	8	LANGERMANN et al., "Systemic and Mucosal Immunity Induced by BOG Vector Expressing Outer-Surface Protein A of Borrelia Burgdorfen", Nature, 372 552-5 (1994)	
	9	LEE et al., "T-Cell Epitope Mapping of the Three Most Abundant Extracellular Proteins of Mycobecterium Tuberculosis in Outbred Guinea Pigs", Infection and Immunity, 67:2665-70 (1999)	
	10	NAITO et al., "The Antigen 85 Complex Vaccine Against Experimental Mycobacterium Leprae Infection in Mice", Vaccine, 19:795-8 (2000)	
	11	OHARA et al., "Characterization of the Transcriptional Inflation Regions of Genes for the Major Secreted Protein Antigens 85C and MPBS1 of Mycobacerium Bovis BCG*, Microbial Pathogenesis, 23:303-10, (1997)	
	12	OHARA et al., "Inhibition of Multiplication of Mycobacterium Leprae in Mouse Foot Pads by Recombinant Bacillus Calmette-Guerin (BCG)", Vaccine, 19:1294-7 (2000)	
	13	STOVER et al., "New Use of BCG for Recombinant Vaccines", Nature, 351.456-60 (1991)	
	14	STOVER et al., "Protective Immunity Elicited by rBCG Vaccines", Dev. Biol. Stand., 82:163-70 (1694)	
	15	STOVER et al., "Protective Immunity Elicited by Recombinant Bacille Calmette-Guerin (BCG) Expressing Outer Surface Protein A (OspA) Lipoproten: A Candidate Lyme Disease Vaccine", J. Exp. Med., 178.197-209 (1993)	
	16	STOVER et al., "Use of Recombinant BCG as a Vaccine Delivery Vehicle", Advances in Experimental Medicine and Biology, 327: 175-82 (1992)	
	17	YASUTOMI et al., "Immunization with Recombinant BCG-SIV Elicits SIV-Specific Cytoloxic T. Lymphocytes in Rhesus Monkeys", The Journal of Immunology, 150:3101-7 (1993)	
If you wis	h to ac	dd additional non-patent literature document citation information please click the Add button Add	

	Application Number		10595385	
INFORMATION DIGGS COURT	Filing Date		2006-04-13	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	First Named Inventor	Marc	us A. Horwitz	
(Not for submission under 37 CFR 1.99)	Art Unit			
(,	Examiner Name			
	Attorney Docket Numb	er	51326-00019	

Examiner Signature	Date Considered		
*EXAMINER: Initial if	reference considered, whether or not citation is in conformation	ance with MPEP 609	Draw line through a

citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 See Kine Codes of USPTO Patent Documents at work_USETO_GCV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (NPPO, Standard ST.3). ³ Per Juponese patent documents, the obtained or the year of the regin of the Emperor met precede the sensit is under of the patent document. ³ Hind of document or by appropriate enteriors are discalated not document. ³ Hind of document or by appropriate enteriors are discalated in document under Wind Obstanderd ST.14 Bessoles. ³ Applicated is to place a check microscopic application at the patent document.

English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 GFR 1.99)

Application Number		10595385
Filing Date		2006-04-13
First Named Inventor Marc		us A. Horwitz
Art Unit		
Examiner Name		
Attorney Docket Number	er .	51326-00019

CERTIFICATION STATEMENT

Please see	37	CER .	1 97	and	1 02	to	make the	annro	nniata	colo	ction	í۰۱	ı

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 197(a)(1).

OR

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquity, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 156(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 197(s)(c).

- 7 See attached certification statement.
- Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- □ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

_			
Signature	/Michelle S. Glasky/	Date (YYYY-MM-DD)	2006-07-17
Name/Print	Michelle S. Glasky, Ph.D.	Registration Number	54124

This collection of information is required by 3T CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is for life and by the USPTO to process) an application. Confidentiality is governed by \$5 U.S. C.12 and 3T CFR.

1.14. This collection is estimated to take I hour to complete, including gathering, preparing and submitting the completed application from the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, u.S. Operatment of Commence, P. O. Box 1430, Alexandriu, V.S. 2213.1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, V.A. 2213.1450.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patient application or patient. Accordingly, pursuant to the requirements of the Act, please be advised that. (1) the general authority for the collection of this information is \$3 U.S.C. 2(b)(2); (2) familishing of the information solicided is columbing, and (3) the principal purpose for which the information is used by the U.S. Patient and Trademan Koffice is to process and/or examine your submission related to a patient application or patient. If you do not furnish the requested process and/or examine your submission related to a patient application or patient. If you do not furnish the requested required to the process and/or examine your submission related to a patient application or patient. If you do not furnish the requested required to the process of the process of the patient application or patient. If you do not furnish the requested process and the process of the patient application or patient. If you do not furnish the required process of the process of the patient application or patient. If you do not furnish the required process of the patient patient process of the patient proc

The information provided by you in this form will be subject to the following routine uses:

- The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
 - A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement neodiations.
 - A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record partains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
 - A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974. as amended, pursuant to 5 U.S.C. 552a(m.).
 - A record related to an International Application filed under the Patent Cooperation Treaty in this system of records
 may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant
 to the Patent Cooperation Treaty.
 - A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or hisher designe, cuting an inspection of records concluded by GSAs and of that agency's responsibility to recommend improvements in records management practices and programs, under suthority of 4d U.S.C. 2004 and 2006. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S. C. 122(b) or issuance of a patent pursuant to 35 U.S. C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 11.4, as a routine use, to the public if the record via 96 flow an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application gone to public insepections or an issuand patent.
 - A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.